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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/814,422	03/21/2001	Emin Tuncay Ustuner	10593/4	4075

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EXAMINER

PANTUCK, BRADFORD C

ART UNIT PAPER NUMBER

3731

DATE MAILED: 10/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/814,422

Applicant(s)

USTUNER, EMIN TUNCAY

Examiner

Bradford C Pantuck

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-72 is/are pending in the application.
- 4a) Of the above claim(s) 1-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 48-56, 59-61 and 65-72 is/are rejected.
- 7) ☒ Claim(s) 57-58 and 62-64 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5. 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Claims 48-72 in Paper No. 7 is acknowledged. The traversal is on the ground(s) that Claims 1-47 may be efficiently searched with Claims 48-72. This is not found persuasive because Claims 1-47 contain many parameters not required by the method claims 48-72. Also, the method could be performed using a different device than the one claimed in Claims 1-47. The requirement is still deemed proper and is therefore made FINAL.

Claim Objections

2. Claim 50 is objected to because of the following informalities: indented section “(c)” would be better named “(d)” since section (c) was already described as “cutting the suture on both sides of the knot with the suturing device after (b)” in Claim 49. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. Claims 52 and 54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The Applicant claims that the second end of the suture passes through at least one of the coils *before being gripped by the gripping element*. However, in the

Specification, the Applicant specifies that the action that pulls the second end of the suture through the coils is when the gripping element engages with the second end and pulls the suture through the coils [page 8, lines 22-28]. Further, the Applicant shows the needle bringing the enlarged element 343 to the position shown in Figure 3b, and says that this position is the “fully extended” position of the needle [page 8, line 19]. The plain meaning of the terms “fully extended” is that the needle cannot extend any farther. The second end of the needle extends through coils *only after it has engaged with gripping element 370*, as shown in Figure 3c and described on page 8, lines 22-28.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 59 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what is meant by the word “between” in this context. For example, in Figure 3c the spacer 380 is *not between* the coils 344 and the second end of the suture.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 51, 53, 55, 56, 67, and 68 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,234,443 to Phan. Regarding Claims 51 and 53, Phan discloses a method of applying and tying a surgical suture, according to the claimed invention. His method includes providing a suturing device with a handle (30 & 65) at one end and a suture delivery system at the other. The suture delivery system includes a suture (150/350) wrapped in a set of coils/partially tied knots. Figure 4A shows the suture wrapped in one coil (155) and Figure 6B shows the suture wrapped in a set of coils [Column 8, lines 62-68]. Both are considered to be partially tied knots. A partially tied knot is understood to be a loop that is on its way to being a knot.

Phan discloses a suture carrier (20), which is a line passing through at least one of the coils [see Fig. 4B; Column 7 line 59 through Column 8 line 9]. Phan also discloses a gripping element (50) configured to grip the second end of the suture [Column 7, lines 65-67]. Phan discloses a needle guide (60) and a needle slideably mounted in the needle guide. The needle guide (60) includes a shaft (70) and jaws (81), which are flat [Column 7, lines 23-30]. His device also has a frame (90) [see Fig. 5]. When the needle is mounted in the flat jaws, the needle will inevitably be slideable.

Phan's method includes steps (b) through step (e), as claimed by the Applicant. He discloses passing the second end of the suture with the needle through tissues to be secured together [Column 7 lines 59-64]. Next, he discloses gripping the second

end (156) of the suture with the suture carrier (20) near the second end (50) of the line. Then he discloses moving the second end of the suture through at least one of the coils [Column 8, lines 5-7]. Lastly, he discloses tightening the first and second ends of the suture [Column 8, lines 7-8].

6. Regarding Claims 55 and 56, Phan discloses a suture delivery system in which the suture is wrapped around a tube (20) [Fig. 4B].
7. Regarding Claim 67, Phan *implicitly* discloses cutting the suture on both sides of the knot after tying the knot. Phan tells us that the intent of his invention is to close internal tissues that have been opened up for one reason or another [Column 1, lines 40-44]. His procedure is performed endoscopically and then his device is removed from the body. Obviously, Phan will want to remove the dangling/long ends of the knot that will only interfere with the body and not serve any purpose. He will need to cut the side of the suture with the needle (153) attached to it in order to remove the needle from the body.
8. Regarding Claim 68, Phan implicitly discloses a delivery system that is capable of suturing repeatedly. It has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8. It is clear that Phan's invention can be used again with another suture.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this

subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 48-50, 60, 61, 65, 66, and 69-72 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,086,601 to Yoon. Regarding Claim 48, Yoon discloses a method of applying and tying a surgical suture, including providing a handle (62/64) at one end and a needle (N) and a suture (S) at the other end. Yoon discloses triggering the handle [Column 8 line 66 to Column 9 line 10] in order to pass the needle (N) and the suture (S) through tissues (T) to be held together, forming a knot, and then tightening then knot [see progression from Figure 7 to Figure 20]. All of these procedures are performed with the suturing device by itself, as is clearly shown in the Figures.
10. Regarding Claim 49, Yoon discloses cutting the suture on both sides of the knot with the suturing device after tying the knot [Column 7, lines 56-69; Column 9, line 67 to Column 10 line 2].
11. Regarding Claim 50, Yoon discloses providing a plurality of sutures [Column 11, lines 11-16]. The procedure disclosed above can be repeated again and again, at the discretion of the surgeon.
12. Regarding Claims 60, 61, 65, 66, 69, and 71, Yoon discloses a method for applying and tying a surgical suture. His method includes providing a suturing device with a handle (62/64) at the proximal end [see Fig. 1]. At the distal end are a needle (N) and a suture (S) [see Fig. 7]. *All* of the actions of handling the needle and applying and tying the knot are performed by triggering the handles (62/64) [Column 6, lines 37-56; Column 10, lines 42-60]. Yoon first passes the needle through two

tissues to be held together [Column 8, line 59 to Column 9, line 7]. Then he forms loops (“stitches”). These can also be called partially tied knots. Then he tightens the first loop [Column 9, lines 21-26 and 66-67].

Each time Yoon makes another “hitch” (a.k.a. loop) in the knot the first hitch (loop) will be tightened because the loop above it, while it is being tightened, will push down and tighten the second loop. When the top “first loop” is tightened a certain amount—to a threshold tension—the first loop will be tight enough to automatically push down on the bottom “second loop” and further tighten it.

After tying the first loops (hitches), Yoon again triggers the handle (62/64) and performs the same acts as the Applicant. Yoon tightens the next hitch and then cuts the suture on both sides of the second loop [Column 7, lines 56-60]. It should be noted again that the handles (62/64) move the end effectors (40 & 50) to perform all of these functions. Yoon will obviously cut the two ends of the suture *after* completing the knot tying procedure, since cutting is well known in the art to be the last part of this type of surgery.

13. Regarding Claims 70 and 72, Yoon discloses a delivery system that is meant for suturing repeatedly. Additional suture material is stored within the device and after one suturing procedure has been accomplished, suture is reattached to the needle and another procedure can be performed [Column 8, lines 8-25]. It is clear that Yoon’s invention can be used again with another suture—that his device is not meant to be disposed of after each use.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent No. 5,769,862 to Kammerer et al.

U.S. Patent No. 6,221,084 B1 to Fleenor

U.S. Patent No. 5,643,293 to Kogasaka et al.

U.S. Patent No. 5,665,096 to Yoon

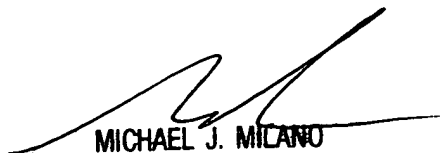
U.S. Patent No. 4,935,027 to Yoon

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradford C Pantuck whose telephone number is (703) 305-8621. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J Milano can be reached on (703) 308-2496. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

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